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The efficacy and safety of new moisturizing cream for dry skin condition and itch relief

Submission date
10/06/2013

Recruitment status
No longer recruiting

Registration date
20/06/2013

Overall study status
Completed

Last Edited
15/05/2014

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to establish the effectiveness and safety data of a new moisturizing cream, which is approved by the Korean Food and Drug Administration for dry skin conditions and itch relief. The results of this study will be used to present the evidence for advertising/display allowances to comply with the recently amended Cosmetic Act for advertisement.

Who can participate?
We will recruit 66 healthy male and female, aged 20 to 65 years diagnosed with dry skin conditions.

What does the study involve?
Participants will be randomly allocated to either receive new moisturizing cream or placebo (dummy) cream for four weeks. Each participant will be examined for signs and symptoms before and after using the cream. Skin hydration, sebum (oily secretion) content and transepidermal water loss (constitutive loss of water from the skin surface) will be assessed. Participants will also be asked to fill out a health-related quality of life questionnaire. Safety will be assessed by blood tests, urine analysis, pregnancy test, and vital signs.

What are the possible benefits and risks of participating?
The results will help to evaluate the effectiveness and safety of new moisturizing cream for dry skin condition and itch relief. It can therefore be considered a suitable preparation that may be used effectively by most patients with dry skin conditions.

Where is the study run from?
This study has been set up by the Wonkwang University Oriental Medical Center in collaboration with Coreana Cosmetics (Co., Ltd.).

When is study starting and how long is it expected to run for?
The study started in April 2013 and is expected to run till October 2013.

Who is funding the study?
Korea Health Industry Development Institute

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A10301712131160101

Study information

Scientific Title
The efficacy and safety of new moisturizing cream for dry skin condition and itch relief: a randomized, double-blind, placebo-controlled trial

Study objectives
This study is aimed at proving the efficacy and safety data of a new moisturizing cream, which is approved by the Korean Food and Drug Administration, for dry skin condition and itch relief.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wonkwang University Oriental Medical Centre Ethics Committee approved on 3rd April 2013

Study design

Randomized double blind two arm placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dry skin condition in healthy volunteers

Interventions
New moisturizing cream or placebo cream will be applied to the affected areas of skin, on the inner surface of left forearm and right side of the face after washing, twice daily (morning and evening), for four weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Efficacy: Measured Day 1, Day 15 and Day 29
1. Measurement of skin hydration (Corneometer)
2. Measurement of sebum content (Sebumeter)
3. Measurement of transepidermal water loss (Tewameter)

Secondary outcome measures
Efficacy:
1. Measurement of stratum corneum content (Corneofix). Measured on day 1, day 15 and ay 29
2. Visual analogue scale (VAS)-xerosis, VAS-itching. Measured on day 1, day 15 and day 29
3. Dermatology Life Quality Index (DLQI), Euro-Qol 5-Dimension (EQ-5D) and Health Utilities Index Mark 3 (HUI-ḉó). Measured on day 1 and day 29

Safety:
1. Vital signs- measured during screening, day 1, day 15 and day 29
2. Blood chemistry- measured during screening and day 29
3. Complete blood cell count, erythrocyte sedimentation rate- measured during screening and day 29
4. Urine analysis- measured during screening and day 29

5. Pregnancy test- measured during screening
6. Picture on the skin lesion and adverse events evaluation- measured on day 1, day 15 and day 29

Overall study start date
10/04/2013

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Volunteer individuals aged 20 to 65 years, either sex
2. Written and informed consent
3. Healthy volunteers without skin disease or any other diseases (acute or chronic)
4. Diagnosed with dry skin condition by the doctor (Korean Medicine), or presented with itching or dry skin condition
5. Available for follow-up observations during clinical trial period

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Pregnancy, lactating, or planned pregnancy
2. People who use external application containing steroids for the treatment of skin disease more than one month
3. Participated in the same trial within six months from the interview
4. People with hypersensitive skin
5. Skin abnormalities such as severe acne, erythema, telangiectasia on the test site
6. Used the same or similar cosmetic (or pharmaceutical) on the test site within three months from the interview
7. Have peeling of skin or wrinkles removed within six months from the interview
8. Other unsuitable reasons for clinical trial based on the discretion of the investigator

Date of first enrolment
10/04/2013

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
Korea, South

Study participating centre
Wonkwang University Oriental Medical Center
Gunpo
Korea, South
435-040

Sponsor information

Organisation
Korea Health Industry Development Institute (KHIDI) (South Korea)

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Sponsor type
Research organisation

Website
http://www.khidi.or.kr/eng/index.jsp

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Research organisation

Funder Name
Korea Health Industry Development Institute (KHIDI) (South Korea)

Alternative Name(s)
KHIDI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/11/2013		Yes	No